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DATE MAILED: 03/20/2009

### NOTICE OF ALLOWANCE AND FEE(S) DUE

2675 7590 03/20/2009 WILLIAM W. HAEFLIGER 201 S. LAKE AVE SUITE 512 PASADENA, CA 91101 EXAMINER
SOROUSH, LAYLA
ART UNIT PAPER NUMBER
1617

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/826,901	04/19/2004	Hovanes John Ter-Zakarian	12,616	2222	
TITLE OF INVENTION: FME TREATMENT					

APPLN, TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(8) DUE	DATE DUE
nonprovisional	YES	\$755	\$0	\$0	\$755	06/22/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This appropriate. All further indicated unless correcte maintenance fee notificat	form should be used to correspondence including d below or directed oth ions.	or trans ig the P ierwise	mitting the ISSU atent, advance or in Block 1, by (a	TE FEE and PUBLE ders and notification of specifying a new of	of n	ON FEE (if requi- naintenance fees w pondence address;	red). I vill be and/or	Blocks 1 through 5 st mailed to the current (b) indicating a sepa	nould be completed where correspondence address as rate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block I for any change of address)				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.					
WILLIAM W. 201 S. LAKE A' SUITE 512	VE	/2009			I ber	Cer	tificate	of Mailing or Trans	
PASADENA, C.	A 91101								(Depositor's name)
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APPLICATION NO.	FILING DATE			FIRST NAMED INVENTOR			ATTORNEY DOCKET NO.		CONFIRMATION NO.
10/826,901 TITLE OF INVENTION	04/19/2004 FMF TREATMENT		I	Hovanes John Ter-Zal	karian	1		12,616	2222
APPLN, TYPE	SMALL ENTITY	ISS	UE FEE DUE	PUBLICATION FEE I	OUE	PREV. PAID ISSU	SFEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES		\$755	\$0		\$0		\$755	06/22/2009
			ART UNIT	CLASS-SUBCLAS	s	1			
	SOROUSH, LAYLA		1617	514-311000					
"Fee Address" indi PTO/SB/47; Rev 03-0 Number is required.  3. ASSIGNEE NAME A	ondence address (or Cha //122) attached. cation (or "Fee Address 2 or more recent) attach ND RESIDENCE DAT/ ess an assignee is ident n in 37 CFR 3.11. Comp	nge of C  Indicated. Use	Correspondence ion form of a Customer  E PRINTED ON 3	(1) the names of or agents OR, alte (2) the name of a registered attorne 2 registered paten listed, no name wi	up to rnativ single y or a t attor ill be or typ the pa	e firm (having as a agent) and the nam meys or agents. If printed. ee) atent. If an assign assignment.	memb es of u no nan	er a 2p to be is 3	cument has been filed for
Please check the appropri		categor					_	on or other private gro	up entity Government
4a. The following fee(s) are submitted:  Issue Fee Publication Fee (No small entity discount permitted) Advance Order - # of Copies				A check is enclo Payment by cred The Director is h	sed. it care ereby	d. Form PTO-2038	is atta	ched. required fee(s), any de	
	SMALL ENTITY state	is. See 3	7 CFR 1.27.					FITY status. Sec 37 CE	
NOTE: The Issue Fee and interest as shown by the r	I Publication Fee (if req ecords of the United Sta	uired) w tes Pate	ill not be accepted and Trademark	from anyone other t Office.	han th	he applicant; a regi	stered.	attorney or agent; or th	e assignee or other party in
Authorized Signature				Date					
Typed or printed name				Registration No.					
This collection of inform an application. Confident submitting the completed this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	ation is required by 37 C iality is governed by 35 application form to the ons for reducing this but irginia 22313-1450. DC 13-1450.	FR 1.31 U.S.C. USPTO rden, she O NOT S	The informatic 122 and 37 CFR     Time will vary ould be sent to the END FEES OR	on is required to obtai 1.14. This collection depending upon the e Chief Information O COMPLETED FORM	n or n is esti indiv Office IS TO	etain a benefit by t imated to take 12 i idual case. Any co r, U.S. Patent and D'THIS ADDRESS	he pub minuter mment Trader i. SEN	tic which is to file (and to complete, includin s on the amount of tir nark Office, U.S. Depa D TO: Commissioner I	by the USPTO to process) g gathering, preparing, and ne you require to complete utment of Commerce, P.O. for Patents, P.O. Box 1450,

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WILLIAM W. H.	AEFLIGER	SOROUSI	H, LAYLA	
201 S. LAKE AVE	Ç		ART UNIT	PAPER NUMBER
SUITE 512 PASADENA CAS	01101		1617	

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 487 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 487 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Notice of Allowability

Application No.	Applicant(s)						
10/826,901	TER-ZAKARIAN, HOVANES JOHN						
Examiner	Art Unit						
LAYLA SOROUSH	1617						

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- This communication is responsive to Pre Appeal Brief 11/24/08.
- The allowed claim(s) is/are 1 and 3-5.
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - b) ☐ Some\* c) ☐ None of the: a)  $\square$  All
    - 1. T Certified copies of the priority documents have been received.
    - 2. Certified copies of the priority documents have been received in Application No.
    - 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) hereto or 2) to Paper No./Mail Date
  - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. 

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- 1. | Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08). Paper No./Mail Date
- 4. T Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7. X Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance
- 9. ☐ Other .

Application/Control Number: 10/826,901

Art Unit: 1617

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with William W. Haeliger on March 12, 2009. This application has been amended as follows:

In claim 1, line 2 delete "patient" and insert - human -- .

In claim 1, line 3 delete "only".

In claim 3, line 5 **delete** "ZARIFLUCAST" and **insert** - 4-5-cyclopentyloxy-carbonylamino-l-methyl-indol-3-ylmethyl-3-methoxy-N-o-tonylsulfanylbenzamide -- .

In claim 4, line 5 delete "SINGULAIR" and insert - montelukant sodium --

In claim 5, line 2 delete "patient" and insert - human -- .

The following is an examiner's statement of reasons for allowance:

The closest prior arts of record, namely Frenkel et al., Sims, and Sawyer et al. either alone or in combination do not teach the treatment of FMF with specific leukotreine receptor antagonists, Zafirlukast or Singulair, the leukotreine receptor antagonists in a low dosage between 5 and 15 milligrams, administered on a daily basis, for periods of time varying from 5 months to 2 1/2 years of claim 3, or to humans between the age of 9 and 72 years of claim 5.

Accordingly, the claims are found to patentable over the prior art.

Application/Control Number: 10/826,901

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on 8:30a.m.-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617

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